Citation:

Stull AJ, Apolzan JW, Thalacker-Mercer AE, Iglay HB, Campbell WW. Liquid and solid meal replacement products differentially affect postprandial appetite and food intake in older adults. *J Am Diet Assoc*. 2008 Jul;108(7):1226-30.

PubMed ID: <u>18589034</u>

Study Design:

Randomized cross-over study

Class:

A - <u>Click here</u> for explanation of classification scheme.

Research Design and Implementation Rating:



NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To assess the effects of liquid versus solid meal replacements on appetite and subsequent food intake in healthy older adults.

Inclusion Criteria:

Individuals were included in the study if the following criteria was met:

- 50 80 years of age
- BMI (kg/m2) 22 to 30
- non-diabetic
- clinically normal kidney, liver and cardiac functions
- NOT taking medications or supplements known to influence appetite
- women 2 + years postmenopausal

Exclusion Criteria:

Individuals were excluded from this study if:

- under 50 years or over 80 years of age
- BMI less than 22 or greater than 30
- diabetes is present
- kidney, liver or cardiac functions are not clinically normal
- taking medication or supplements known to influence appetite

Data from participants (n=12) was excluded from the study for the following reasons:

- schedule conflicts
- inability to tolerate meal replacements and/or subsequent food (oatmeal)

- consumption of all subsequent food (oatmeal)
- undue influence (witness to another subject food intolerability) on response to intervention
- statistical outliers

Description of Study Protocol:

Recruitment

Participants (n=36) were recruited from greater Lafayette, IN community using newspaper advertisements

Design randomized crossover design

Blinding used (if applicable)

none

Intervention (if applicable)

A within subject design was used. Each subject completed 2 days of testing (random order) separated by one week. At each day of testing subjects:

- presented in a fasting state
- consumed either a liquid (Ensure Complete Balanced Nutrition) or solid (Ensure Cinnamon Oat'n Raisin nutrition and energy bar) meal replacement in seclusion within 15 minutes of arrival
- waited 2 hours (120 minutes) before consumption of bowl of hot oatmeal (each bowl: rolled oats (120 g dry weight), 2% reduced-fat milk (75 g) brown sugar (24 g), salt (1 g) and water 550 g), representing 3 commercial servings. Total amount consumed was quantified by weight the bowl before and after the subject ate
- had appetite assessed at baseline, 15, 30, 45, 60, 90 and 120 minutes after meal replacement consumed
- had appetite assessed again 30 minutes after oatmeal consumption

Statistical Analysis

- AUC (Appetite ratings area under curve): assessed using repeated measure analysis of variance with meal replacement products as repeated effects in the models
- Paired t-test: to assess difference between liquid and solid before the meal replacement product was consumed (baselne, minute 0) and after consumption of the oatmeal (minute 15)

Data Collection Summary:

Timing of Measurements

Appetite was assessed at:

- baseline, 15, 30, 45, 60, 90 and 120 minutes after meal replacement consumed and
- again 30 minutes after oatmeal consumption

Appetite was measured by rating (using a visual analog scale):

- perceived hunger
- feelings of fullness
- desire to eat
- preoccupation with thoughts of food

Dependent Variables

- hunger rating
- desire to eat rating
- preoccupation with thoughts of food
- fullness
- food intake

Independent Variables

- consumption of solid meal replacement
- consumption of liquid meal replacement

Control Variables

none

Description of Actual Data Sample:

Initial N: number of participants

n = 36

Attrition (final N):

n=24 (12 M, 12F)

Age:

ages 50 -80 years (mean = 62 ± 2 years)

Ethnicity:

no information available

Other relevant demographics:

None available

Anthropometrics

Mean BMI = 26 ± 0.8

Location:

Lafayette, Indiana

Summary of Results:

Key Findings:

- No significant differences in desire to eat, preoccupations with thoughts of food and fullness between liquid and solid meal replacements products
- Hunger was higher for liquid versus solid meal replacement products
- Subjects consumed 13.4% *more* food at next eating occasion after injesting liquid versus solid meal replacement ($338 \pm 33 \text{ vs } 298 \pm 32 \text{ kcal}$; P=0.006)

Variables (mm)	Consumption of liquid meal replacement	Consumption of solid meal replacement	Difference Statistical
AUC for hunger	2071 ±607	1498 ± 439	Significance (p) statistically significant difference
AUC for desire to eat	2117 ± 612	1776 ± 521	(p= 0.04) no significant difference
AUC for preoccupation with	1650 ±500	1352 ±397	(p=0.15) no significant difference
food AUC for fullness	4513 ±806	5136 ±1149	(p = 0.07) no significant difference
			(p=0.25)

Author Conclusion:

The author suggests that the ingestion of a meal replacement in a liquid form elicts a blunted post-prandial decline in hunger as well as higher food intake at the next eating occasion. Therefore, it can be concluded that the physical form of the food influences appetite and ingestive behavior.

Reviewer Comments:

Overall this study has a strong design as evidenced by the controlled research environment, continuous supervision of participants and the use of a diversionary task to reduce the chance of biased responses.

The use of commonly-used meal replacement products, makes the implications of this research practical and useful to the dietetics profession. However, due to the small number of participants, it is not clear if the results could be generalized or achieved in other population groups.

Research Design and Implementation Criteria Checklist: Primary Research					
Rele	Relevance Questions				
	1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes		
	2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes		
	3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes		
	4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes		
Valid	dity Questions				
1.	Was the reso	earch question clearly stated?	Yes		
	1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes		
	1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes		
	1.3.	Were the target population and setting specified?	Yes		
2.	Was the sele	ection of study subjects/patients free from bias?	Yes		
	2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes		
	2.2.	Were criteria applied equally to all study groups?	Yes		
	2.3.	Were health, demographics, and other characteristics of subjects described?	Yes		
	2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes		
3.	Were study	groups comparable?	???		
	3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	No		
	3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A		
	3.3.	Were concurrent controls used? (Concurrent preferred over	Yes		

historical controls.)

	3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
	3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
	3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method	l of handling withdrawals described?	Yes
	4.1.	Were follow-up methods described and the same for all groups?	Yes
	4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
	4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
	4.4.	Were reasons for withdrawals similar across groups?	???
	4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blindin	g used to prevent introduction of bias?	Yes
	5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
	5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
	5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
	5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
	5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.		ention/therapeutic regimens/exposure factor or procedure and ison(s) described in detail? Were interveningfactors described?	Yes
	6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
	6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A

	6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
	6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
	6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
	6.6.	Were extra or unplanned treatments described?	N/A
	6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
	6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcom	mes clearly defined and the measurements valid and reliable?	Yes
	7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
	7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
	7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
	7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
	7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
	7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the stat	tistical analysis appropriate for the study design and type of licators?	Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
	8.6.	Was clinical significance as well as statistical significance reported?	Yes

	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	Are conclust consideration	ions supported by results with biases and limitations taken into on?	Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due t	to study's funding or sponsorship unlikely?	Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes

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